

**Claims:**

1. A method for the diagnosis of a neurodegenerative disorder in a mammalian subject comprising:
  - a. providing a body fluid sample of said subject;
  - b. concentrating proteins comprised within said sample by suitable means;
  - c. contacting the concentrated sample obtained in step (b) with a sufficient amount of a protein which has a beta-sheet structure, under conditions suitable to allow the formation of aggregates, said aggregates comprise a protein associated with said neurodegenerative disorder; and
  - d. measuring aggregate formation by suitable means, whereby the presence of aggregates in said sample indicates that said subject carries said neurodegenerative disorder.
2. The method according to claim 1, wherein the measurement of aggregate formation in said step (d) comprises the following steps:
  - (i) adding to the mixture obtained in step (c) a binding material capable of binding aggregates of proteins associated with said neurodegenerative disorder;
  - (ii) applying the sample obtained in step (i) onto a solid support; and
  - (iii) detecting a visual signal which indicates the presence of aggregates comprising a neurodegenerative disorder- associated protein in said tested sample.
3. The method according to claim 2, optionally further comprising the step of separating said aggregates from said mixture by suitable means, prior to the addition of said binding material.

4. The method according to claim 3, wherein said suitable means is selected from the group consisting of proteinase K digestion, dialysis and centrifugation.
5. The method according to any one of claims 2 to 4, wherein said binding material is selected from the group consisting of an antibody, a peptide, a substance having affinity to a specific compound in said aggregate and specific dye.
6. The method according to claim 5, wherein said specific dye is any one of Congo Red, Thioflavin-T and Thioflavin-S.
7. The method according to claim 6, wherein said specific dye is Congo Red.
8. The method according to claim 5, wherein said binding material is an antibody which specifically recognizes said protein which has a beta-sheet structure.
9. The method according to any one of claims 1 and 8, wherein said protein which has a beta-sheet structure is selected from the group consisting of IgG light chain (LC), human Bence Jones (BJ) protein and recombinant PrP protein.
10. The method according to claim 9, wherein said protein which has a beta-sheet structure is IgG light chain (LC).
11. The method according to claim 1, wherein said neurodegenerative disorder is any one of Alzheimer's disease, multiple sclerosis, and spongiform encephalopathy.

12. The method according to claim 11, wherein said spongiform encephalopathy is any one of Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker Syndrome (GSS), Kuru, scrapie and bovine spongiform encephalopathy (BSE).
13. The method according to claim 12, wherein said mammalian subject is selected from the group consisting of humans, sheep, goats, bovines, minks, hamsters and cats.
14. The method according to claim 1, wherein said body fluid sample is selected from the group consisting of: blood, lymph, milk, urine, faeces, semen, brain extracts, spinal cord fluid (SCF), appendix, spleen and tonsillar tissue extracts samples.
15. The method according to claim 14, wherein said body fluid sample is a urine sample.
16. The method according to claim 1, wherein concentrating the proteins in said sample is performed by centrifugation and precipitation.
17. The method according to any one of claims 12 to 16, wherein said neurodegenerative disorder-associated protein is the abnormal isoform of prion protein (PrP<sup>Sc</sup>).
18. A method for the diagnosis of a spongiform encephalopathy in a mammalian subject comprising:
  - (a) providing a urine sample of said subject;
  - (b) concentrating proteins comprised within said sample;
  - (c) contacting the concentrated sample obtained in step (b) with a sufficient amount of IgG LC, under conditions suitable to allow

- the formation of aggregates, which aggregates comprise the abnormal isoform of prion protein (PrP<sup>Sc</sup>);
- (d) adding Congo Red to the sample mixture obtained in step (c), in an amount sufficient for detection of aggregates comprising the abnormal isoform of the prion protein (PrP<sup>Sc</sup>);
  - (e) applying the sample obtained in step (d) onto a nitrocellulose membrane; and
  - (f) detecting a visual signal indicating the presence of aggregates comprising the abnormal isoform of prion protein (PrP<sup>Sc</sup>) in said tested urine sample; whereby the presence of said aggregates in said sample indicates that said subject carries a prion disease.
19. The method according to claim 18, wherein said spongiform encephalopathy is any one of Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker Syndrome (GSS), Kuru, scrapie and bovine spongiform encephalopathy (BSE).
20. The method according to claim 19, wherein diagnosis of said spongiform encephalopathy is performed prior to or after onset of clinical symptoms.
21. A method for detecting the presence of a neurodegenerative disorder-associated protein in a sample of a subject, said method comprising the steps of:
- (a) providing a body fluid sample of said subject;
  - (b) concentrating proteins comprised within said sample by a suitable means;
  - (c) contacting the concentrated sample obtained in step (b) with a sufficient amount of a protein which has a beta-sheet structure, under conditions suitable to allow the formation of aggregates, which

aggregates comprising said neurodegenerative disorder-associated protein; and

(d) measuring aggregate formation by suitable means.

22. The method according to claim 21, wherein the measurement of aggregate formation in step (d) comprises the following steps:
  - (i) adding to the mixture obtained in step (c), a binding material capable of binding aggregates of proteins associated with said neurodegenerative disorder;
  - (ii) applying the sample obtained in step (i) onto a solid support; and
  - (iii) detecting a visual signal indicating the presence of aggregates comprising said neurodegenerative disorder-associated protein in said tested sample.
23. The method according to claim 22, optionally further comprising the step of separating said aggregates from said mixture by a suitable means, prior to addition of said binding material.
24. The method according to claim 23, wherein said suitable means is selected from the group consisting of proteinase K digestion, dialysis and centrifugation.
25. The method according to any one of claims 22 to 24, wherein said binding material is selected from the group consisting of an antibody, a peptide, a substance having affinity to a specific compound in said aggregate and specific dye.
26. The method according to claim 25, wherein said specific dye is any one of Congo Red, Thioflavin-T and Thioflavin-S.

27. The method according to claim 26, wherein said specific dye is Congo Red.
28. The method according to claim 25, wherein said binding material is an antibody which specifically recognizes said protein which has a beta-sheet structure.
29. The method according to claim 21, wherein said protein which has a beta-sheet structure is selected from the group consisting of IgG light chain (LC), human Bence Jones (BJ) protein and recombinant PrP protein.
30. The method according to claim 29, wherein said protein which has a beta-sheet structure is IgG light chain (LC).
31. The method according to claim 21, wherein said neurodegenerative disorder is any one of Alzheimer's disease, multiple sclerosis, and spongiform encephalopathy.
32. The method according to claim 31, wherein said spongiform encephalopathy is any one of Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker Syndrome (GSS), Kuru, scrapie and bovine spongiform encephalopathy (BSE).
33. The method according to claim 32, wherein said mammalian subject is selected from the group consisting of humans, sheep, goats, bovines, minks, hamsters and cats.
34. The method according to claim 21, wherein said body fluid sample is selected from the group consisting of blood, lymph, milk, urine, faeces,

semen, brain extracts spinal cord fluid (SCF), appendix, spleen and tonsillar tissue extracts samples.

35. The method according to claim 34, wherein said body fluid sample is a urine sample.
36. The method According to claim 35, wherein concentrating the proteins in said sample is performed by centrifugation and precipitation.
37. The method according to claim 21, wherein said neurodegenerative disorder-associated protein is the abnormal isoform of prion protein (PrP<sup>Sc</sup>).
38. A method for detecting the presence of the abnormal isoform of prion protein (PrP<sup>Sc</sup>) in a urine sample of a subject, said method comprising the steps of:
  - (a) providing a urine sample of said subject;
  - (b) concentrating proteins comprised within said sample;
  - (c) contacting the concentrated sample obtained in step (b) with a sufficient amount of IgG LC, under suitable conditions allowing the formation of aggregates comprising the abnormal isoform of prion protein (PrP<sup>Sc</sup>);
  - (d) adding Congo Red to the sample mixture obtained in step (c), in an amount sufficient for detection of formation of aggregates which comprise the abnormal isoform of prion protein (PrP<sup>Sc</sup>);
  - (e) applying the sample obtained in step (d) onto a nitrocellulose membrane; and
  - (f) detecting a visual signal indicating the presence of aggregates comprising the abnormal isoform of prion protein (PrP<sup>Sc</sup>) in said tested urine sample; whereby the presence of said aggregates in

said sample is indicative of the presence of the abnormal isoform of prion protein (PrP<sup>Sc</sup>) in said sample.

39. A kit for the diagnosis of a neurodegenerative disorder in a mammalian subject, comprising:
  - (a) means for obtaining a sample from a tested mammalian subject;
  - (b) means for concentrating proteins in said sample;
  - (c) a protein which has a beta sheet structure;
  - (d) means for measuring aggregate formation in said sample;
  - (e) optionally, suitable buffers; and
  - (f) instructions for carrying out the detection of the presence of aggregates comprising a neurodegenerative disorder-associated protein in said sample.
40. The kit according to claim 39, optionally further comprising means for separating said aggregates from said sample prior to measuring aggregate formation.
41. The kit according to any one of claims 39 and 40, wherein said means for measuring aggregate formation is a binding material capable of binding said neurodegenerative disease associated protein aggregate.
42. The kit according to claim 41, wherein said binding material is selected from the group consisting of an antibody, a peptide, a substance having affinity to a specific compound in said aggregate and a specific dye.
43. The kit according to claim 42, wherein said binding material is any one of Congo Red, Thioflavin-T and Thioflavin-S.



44. The kit according to claim 43, wherein said binding material capable of binding said neurodegenerative disorder-associated protein aggregate is Congo Red.
45. The kit according to claim 42, wherein said binding material is an antibody which specifically recognizes said protein which has a beta-sheet structure.
46. The kit according to claim 39, further comprising solid support for binding proteins in said sample.
47. The kit according to claim 39, wherein said protein which has a beta-sheet structure is selected from the group consisting of IgG light chain (LC), human Bence Jones (BJ) protein and recombinant PrP protein.
48. The kit according to claim 47, wherein said protein which has a beta-sheet structure is IgG light chain (LC).
49. The kit according to claim 48, wherein said neurodegenerative disorder is any one of Alzheimer's disease, multiple sclerosis, and spongiform encephalopathy.
50. The kit according to claim 49, wherein said Spongiform encephalopathy is any one of Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker Syndrome (GSS), Kuru, scrapie and bovine spongiform encephalopathy (BSE).
51. The kit according to claim 50, wherein said mammalian subject is selected from the group consisting of humans, sheep, goats, bovines, minks, hamsters and cats.

52. The kit according to claim 51, wherein said body fluid sample is selected from the group consisting of blood, lymph, milk, urine, faeces, semen, brain extracts, spinal cord fluid (SCF), appendix, spleen and tonsillar tissue extracts samples.
53. The kit according to claim 52, wherein said body fluid sample is a urine sample.
54. The kit according to claim 53, wherein said neurodegenerative disorder-associated protein is the abnormal isoform of prion protein (PrP<sup>Sc</sup>).
55. Use of a protein which has a beta-sheet structure which enhances the formation of aggregates comprising a neurodegenerative disorder-associated protein, in the preparation of a diagnostic composition for the diagnosis of said neurodegenerative disorder.
56. A diagnostic composition for the detection of a neurodegenerative disorder in a mammalian subject, which composition comprises as an effective ingredient a sufficient amount of a protein which has a beta-sheet structure.
57. The composition according to claim 56, wherein said protein is the IgG LC.